תע	
AD	

Award Number: MIPR OEC5DGM0071

TITLE: Utilization of Telemedicine for Evaluation and Treatment of Hepatitis C Patients in Military Health Clinics

PRINCIPAL INVESTIGATOR: Kent Holtzmuller

CONTRACTING ORGANIZATION: Walter Reed Army Medical Center

Washington, DC 20307-5001

REPORT DATE: October 2001

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave	2. REPORT DATE	3. REPORT TYPE AND			
blank)	October 2001	Final (15 Feb	00 - 30 Sep 01) 5. FUNDING NUMBERS		
4. TITLE AND SUBTITLE Utilization of Telemed:	iding for Evaluation an	d Treatment of	MIPR OEC5		
Hepatitis C Patients in	cine for Evaluation and	cc Treatment Or	MIFR OECS	JGH0071	
Hepatitis C Patients in	military hearth Cilm	.Cs			
6. AUTHOR(S)					
Kent Holtzmuller					
7. PERFORMING ORGANIZATION N		G ORGANIZATION			
Walter Reed Army Medical Center	REPORT NUMBER				
Washington, DC 20307-5001					
E-Mail:					
9. SPONSORING / MONITORING AG	CENCY NAME(S) AND ADDRESS/E	3)	10. SPONSORING / MONITORING		
9. SPONSORING / WONTORING A	GENCT NAME(S) AND ADDRESS(E	3)		EPORT NUMBER	
U.S. Army Medical Research and	Materiel Command				
Fort Detrick, Maryland 21702-50	112				
1 of Detrick, Maryland 21702 30	312				
11. SUPPLEMENTARY NOTES			<u> </u>		
12a. DISTRIBUTION / AVAILABILIT	YSTATEMENT			12b. DISTRIBUTION CODE	
Approved for Public Re	lease; Distribution Unl	limited			
13. ABSTRACT (Maximum 200 Wor	ds)				
14. SUBJECT TERMS				15. NUMBER OF PAGES 9	
			ſ	16. PRICE CODE	
AZ OFOURITY OF ACCIFICATION	18. SECURITY CLASSIFICATION	19. SECURITY CLASSII	FICATION	20. LIMITATION OF ABSTRACT	
17. SECURITY CLASSIFICATION OF REPORT	OF THIS PAGE	OF ABSTRACT			
Unclassified	Unclassified	Unclassified		Unlimited	



DHP RFS Final Report



Utilization Of Telemedicine For Evaluation And Treatment Of Hepatitis C Patients In Military Health Clinics
Proposal Number: 1999000160

Kent C. Holtzmuller M.D.

Abstract

Problems

Two significant problems arose during performance of this project.

- 1. The WRAMC Department of Clinical Investigation (DCI) pre- protocol review of the project determined that approval of the project would not be granted as the protocol was originally proposed. The DCI concerns of the original proposal were twofold. The first concern was that a study to validate the physical exam findings commonly identified in patients with liver disease could be identified via VTC had not previously been performed. The second concern was that a study to validate that HCV patients being treated with anti-viral therapy could successfully be managed via VTC had not been previously performed. DCI would not approve a protocol to deploy VTC to outlying NARMC clinics to diagnose and manage HCV patients without first validating the technology within WRAMC. This resulted in a change of the protocol to first validate the VTC technology for identifying physical exam findings in patients with liver disease and managing anti-viral therapy in HCV patients within WRAMC prior to deployment throughout the NARMC.
- 2. The second problem in implementing this project has been delay in installing the PRI lines into the Gastroenterology Clinic at Walter Reed and establishing connectivity within the Gastroenterology Clinic. The delay has been twofold. The first was a failure by DOIM to release the PRI lines to the Gastroenterology Clinic and the second was the inability to find a cost effective way to establish connectivity in the Gastroenterology Clinic and within the financial constraints of the protocol. These technical issues have been resolved. PRI lines have been released to the Gastroenterology Clinic and a contract is in place to connect four offices/exam rooms within the Gastroenterology Clinic.

Two secondary problems have been identified to date.

- 1. The Telemedicine facilities at the outlying NARMC medical treatment facilities are located in a conference room and are utilized for in facility conferences, standard video conferencing and Telemedicine consultation. The VTC equipment is frequently unavailable for Telemedicine consultation because of other conferencing uses. The lighting in the conference rooms is poor which reduces the ability to identify dermatological findings. This problem was identified during testing of VTC facilities within the NARMC and performing off protocol Hepatology consultations using the Fort Drum VTC equipment at the Guthrie Health Clinic.
- 2. There was a turnover of outlying NARMC clinic associate investigators in July 2000. Dr. Ratcliffe (Ft Eustis) left the Army and Dr. Toferi (Ft. Knox) transferred to WRAMC. Replacement associate investigators are being sought.

Deliverables

The following deliverables have been completed:

- 1. Pilot study to determine optimal connectivity speed completed (1).
- 2. DCI protocol for the in-house validation of VTC technology to determine diagnostic agreement of visual physical exam findings in patients with hepatitis completed and approved.
- 3. DCI protocol for the in-house validation of VTC technology to manage patients with hepatitis C has been submitted for approval.
- 4. An abstract published and a presentation given from the pilot study data described in #1.
- 1. Hwang I, Cannon BL, Holtzmuller KC, Poropatich RK. Feasibility and cost savings in VTC follow-up of patents treated with combination viral therapy for chronic hepatitis C. Telemedicine Journal 2000;6(1):106. (abstract)

There has been a substantial change in the project compared with the original submission. The project is now focused on validating VTC in identifying the physical exam findings that are commonly found in patients with liver disease and validating VTC in managing patients with hepatitis C who are taking anti-viral medications. The shift in the project design was necessitated by recommendations from the WRAMC DCI. Validation of this technology at WRAMC was necessary prior to deploying this technology to the field in caring for patients.

Expenditures

responding sports on the confidence of the confi	3Q FY 00	4Q FY 00	1Q FY 01	2Q FY 01	The control of the co
Element of Resource (EOR)	Apr 1 - May 31	Jun 1 - Sep 30	Oct 1 - Dec 31	Jan 1 - Mar 31	TOTALS
Travel 2100	0.00	0.00	0.00	2,000.00	2,000.00
Shipping 2200	0.00	0.00	0.00	0.00	0.00
Rent & Communications 2200	0.00	0.00	0.00	0.00	0.00
Contract for Services 2500	42,173.00	0.00	8,315.00	8,315.00	58,803.00
Supplies 2600	0.00	0.00	0.00	0.00	0.00
Equipment 3100	16,655.98	0.00	0.00	122,541.02	139,197.00
GRAND TOTALS	58,828.98	0.00	8,315.00	132,856.02	200,000.00

Financials

This project will use existing desktop VTC technology to enable four VTC-ready physician workstations. Real-time clinical consultations will take place using a 384 kbps connection via the local area network (LAN) connecting to an ISDN wide area connection. Equipment used includes:

? (4) Workstations ? (4) VCON Escort 25 Desktop Systems (camera and microphone) ? Multi-control Unit, IP-based (MCU) - holds IP-based VTC sessions ? Gatekeeper Gateway - converts H.320 and H.323 VTC protocols ? Madge Intelligent Switch - supports three PRI connections - interface between WRAMC LAN and ISDN WAN ? Upgrade 7th floor VLAN switch with 100Mbps switch card ? Upgrade 1st floor VLAN switch, enable (2) 100Mbps ports ? Upgrade OC-3 to OC-12 backbone between 1st and 7th floor VLAN switches ? 3 Dell PC's ? 1 Zydacron 128 ? 1 Zydacron 384 ? Combination lamps

Total cost of the above equipment was 139,197.00

The cost of the equipment to establish connectivity in the WRAMC Gastroenterology Clinic was substantially higher than estimated in the original submission. Personnel costs at the outlying NARMC clinics have not been undertaken because the project has not been deployed within the NARMC. Deployment of the project to the outlying NARMC facilities will not be undertaken until validation is completed at WRAMC.

WRAMC Telemedicine Program * 20,000.00 Research Assistant 38,803 Travel 2000 *The above amount was committed to the WRAMC Telemedicine Directorate for the management of this project. In exchange for this fee, the WRAMC Tmed Directorate managed funds, evaluated and ordered equipment, assisted in protocol development, submitted contracts for services and equipment, and coordinated efforts with the WRAMC DOIM and contracted vendors.

Final Results

The project is ongoing and the final results are not available.

The hepatitis C Telemedicine project is being conducted in three phases. The first phase of the project is to validate the use of desktop VTC system connected at 384 kbps to visually diagnose patients with physical findings secondary to chronic liver disease. Diagnostic agreement between in person, face-to-face evaluations versus those performed using the VTC system is being compared in patients with liver disorders. This first phase of the project was added to the original submitted protocol because of a lack of published literature on the utilization of VTC in evaluating patients with liver disease. It is necessary to ensure that common physical exam findings in patients with liver disease can be identified on a VTC system prior to the institution of this system in caring for patients. DCI approval of a research project to complete this task has been granted. The WRAMC DCI approved protocol is entitled "Tele-Hepatitis Phase I: Validation of desktop Video Teleconferencing (VTC) system at 384 kbps ISDN for evaluation of patients with chronic liver diseases" (WRAMC DCI protocol #00-1407). A pilot project has been completed and presented at the 5th Annual American Telemedicine Association conference in Phoenix, AZ, in May 2000. Data from the first five patient evaluated in the pilot project comparing in person exam versus VTC exam showed that there was moderate agreement in physical exam findings in patients with liver disease but was dependent on the bandwidth utilized. A 384 kbps connection was superior to the 128 kbps connection. Thus, a minimum of 384 kbps connection speed will be utilized in the in-house validation study.

The second phase of the project is to perform validation for managing patients with hepatitis C on anti-viral therapy. The protocol has been submitted to WRAMC DCI for approval. Approval is expected 29 May 01. This second phase of the project was added to the original submitted protocol because of a lack of published literature on the utilization of VTC in managing patients with liver disease. Patients with HCV will be evaluated using traditional in-person, face-to-face exams, as well as VTC- based exams. 112 adult patients currently receiving HCV anti-viral will be evaluated. This study uses a crossover design where the subjects serve as their own controls. Patients will be randomized to one of four exam/rater sequences. The initial physician evaluation is either the in-person or the VTC-based patient evaluation. Immediately following the initial evaluation, a second physician will evaluate the patient by VTC or in-person in a scheme opposite of the first evaluation. Inter-rater agreement of visual physical exam findings and case management decisions between in person patient evaluation versus those performed using the VTC system will be compared. An estimate of cost savings (time and monetary) using VTC conferencing will also be performed.

The third phase of this project will be the deployment of this technology to other sites within the NARMC region. At the current funding level, the expenditures to complete the validation portion of this project will prevent deployment of the third phase of this project.

Validation and successful deployment of this technology to diagnose and manage patients with chronic liver disease will enable access to sub-specialty Hepatology care at all military medical treatment facilities that have access to VTC.

Projected Costs

The costs to sustain this project locally are: 8000 Yearly service maintenance contract fees 60000 Project officer

Additional costs to deploy this project to proposed four NARMC sites for completion of the third phase:

Desktop VTC systems with high-end camera* 8000 x four 32000

Combination Lamps 175 x four 700

Local project officer - part-time 20000 x four 80000

*Each NARMC site will have a dedicated VTC system in a well lighted exam room to perform the consultation. A dedicated system will preclude the problems of availability of the health facility video-conferencing room.

Comments

I have found that most physicians and health care administrators are completely naive or uninterested in the potential that Telemedicine has for improving access to care and decreasing unit travel costs and loss of work productivity. A primary obstacle in the utilization of Telemedicine is the inconvenience of the current system. One has to schedule available time in a central facility VTC unit, ensure that the outlying clinic VTC conference system is available, and coordinate patient and physician schedules to coincide with the openings in the two VTC facilities. It has been my experience in evaluating "off- protocol" patients that this coordination can take up to ten phone calls. Ancillary personnel to coordinate such consultations are not available in our current system. Physicians must also leave their busy clinics to perform the VTC consult resulting in a consultation that take more time than an "in office" consultation. The major selling point of a low cost VTC system is that physicians can perform consultations from their office without going through all the headaches associated with "of out of office" central VTC facilities. It is my belief that once validated, the convenience and efficiency of this technology will be avidly embraced by physicians.

I have also found some patient resistance in accepting the Telemedicine consult/process. There are some military patients who look forward to their trip to Washington, D.C., and the TDY benefits that incur with such a trip. On occasion, I have had to intervene on the unit level to complete a Telemedicine evaluation.

TATRC Scientific Review

TATRC Acquisition Review

Supporting Graphs/Charts

No Attachments